

**COMPARISON OF VISUAL OUTCOME AT ONE YEAR FOLLOWING  
PHOTOREFRACTIVE KERATECTOMY (PRK) AND PHOTOREFRACTIVE  
KERATECTOMY WITH MITOMYCIN C IN HIGH MYOPIA**

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*AIM*

## **AIM**

To compare visual outcome at one year following photorefractive keratectomy (PRK) and photorefractive keratectomy with mitomycin C in high myopia

# *INTRODUCTION*

## **INTRODUCTION**

Myopia / short sightedness is a refractive error in which the parallel rays of light from infinity come to focus in front of the retina when the eye is at rest, thus grossly reducing the vision. Myopia could be axial due to elongation of anteroposterior diameter of the eyeball or curvature myopia due to increase in radius of curvature of the cornea; and index myopia due to change in refractive index of lens, cornea, aqueous and vitreous, thus increasing the dioptric power of the eye.

### **Photorefractive keratectomy (PRK)**

Consists of the application of energy of the ultraviolet range generated by an argon fluoride (ArF) excimer laser to the anterior corneal stroma to change its curvature and, thus, to correct a refractive error. The physical process of remodeling the corneal stroma by ultraviolet (193 nm wavelength) high-energy photons is known as photoablation.

### **History of the Procedure**

During the 1980s, several applications of the 193-nm ArF excimer laser were investigated, including its use on human corneas for the correction of refractive errors. In 1988, Munnerlyn, Kroons, and Marshall reported an algorithm relating diameter and depth of the ablation to the required dioptric change.

McDonald performed the first excimer PRK for the correction of myopia on a normally sighted human eye in the United States. That same year, the Food and Drug Administration (FDA) organized a 3-phase trial, the PRK study (which ended in 1996), to demonstrate the safety, predictability, and stability of PRK for the treatment of myopia. At the end of this trial, 2 ophthalmic companies, VISX and Summit, were allowed to manufacture excimer lasers for widespread use in the United States. Since then, Nidek also has obtained approval for the manufacture of excimer lasers in the United States, and several hundred thousand patients have undergone this procedure throughout the world. The first excimer lasers used to perform PRK in the late 1980s have been improved significantly in terms of size, efficiency, and accuracy.

### **Pathophysiology**

The mechanism of ablation of the excimer laser appears to be photochemical in nature and is known as photochemical ablation or ablative photodecomposition. This highly localized tissue interaction is based on the fact that each photon produced by the ArF excimer laser has 6.4 eV of energy, enough to break covalent bonds.

The efficacy and success of PRK depends largely on the type of laser platform in use. Current fifth generation systems use a very rapidly repetitive and extremely small spot delivery with automated tracking of the eye movements to ensure precise treatment.



The intramolecular bonds of exposed organic macromolecules are broken when a large number of high-energy 193-nm photons are absorbed in a short time. The resulting fragments rapidly expand and are ejected from the exposed surface at supersonic velocities. This mechanism explains why only the irradiated organic materials are affected, whereas the adjacent areas are not affected.

The return of corneal innervation up to 5 years after PRK was measured. Corneal subbasal nerve density does not recover to near preoperative densities until 2 years after PRK, as compared to 5 years after laser in situ keratomileusis (LASIK).

### **Mitomycin C**



Isolated from streptococcus calspitosus in 1958, mitomycin react with DNA in ways similar to alkylating agents. It cross links DNA and inhibits its synthesis. It is highly effective antimitotic agent used in treatment of carcinoma of stomach and colon. The ocular indications for the mitomycin C are recurrent pterygium and glaucoma filtering surgery.

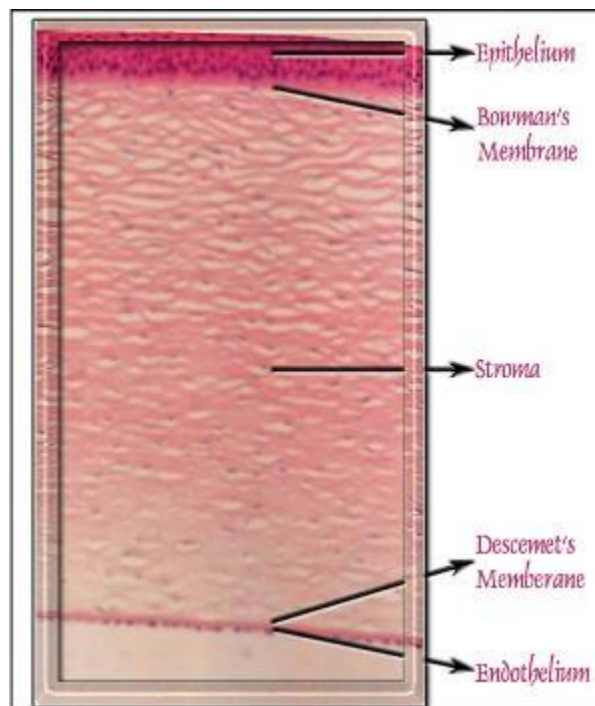
Kulitoma and Mori (1976) reported favorably on the efficacy of mitomycin C eye drops in recurrent pterygium.

### Use of mitomycin C in PRK

They act by inhibiting activated keratocytes, probably by interfering with DNA synthesis, which decreases cellular activity and reduces collagen synthesis. Mitomycin inhibits fibroblast function by a dose dependent inhibition of fibroblast proliferation.

Mujmudar et al and Raviv et al reported mitomycin C efficacy in treating significant pre existing corneal scarring

### Corneal Anatomy



Cornea has five layers

Epithelium (30-50)µm

Bowmans Membrane (10-14)µm

Stroma (500-700µm)

Descemet's Membrane (3-12)

Endothelium (4-6)

The average corneal diameter is 11.5mm (vertical) and 12mm horizontal.

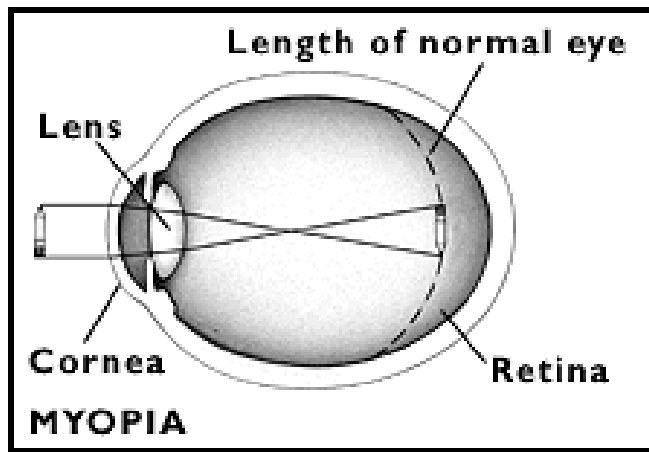
1. Epithelium is stratified squamous and nonkeratinised and comprises
  - ❖ Single layer of columnar cells (basal)
  - ❖ 2 to 3 round wing cells
  - ❖ 2 layers of squamous surface cells
2. Bowman layer is the acellular superficial layer of the stroma, which scars when damaged.
3. The stroma makes up 90% of corneal thickness comprised of regularly oriented layers of collagen fibrils whose spacing is maintained by proteoglycan ground substance (chondroitin sulphate and keratan sulphate) with interspersed modified fibroblasts.
4. Descemet's membrane- fine latticework of collagen fibrils.
5. Endothelium- single layer of hexagonal cells. It plays a vital role in maintaining corneal deturgescence but does not regenerate.

## *REVIEW OF LITERATURE*

## REVIEW OF LITERATURE

### Myopia

Short sightedness is a type of refractive error in which parallel rays of light coming from infinity are focused in front of the retina when accommodation is at rest.



### Mechanism of production

1. Axial myopia results from increase in anteroposterior length of the eyeball. It is the commonest.
2. Curvatural myopia occurs due to increased curvature of the cornea, lens, or both.
3. Positional myopia- anterior placement of crystalline lens in the eye.

4. Index myopia- results increase in RI of crystalline lens associated with nuclear sclerosis.
5. Myopia due to excessive accommodation occurs in patients with spasm of accommodation.

### **Optics of Myopia**

In myopes, a near object may be focused without any effort of accommodation if it is situated at the punctum remotum. The image of an object at infinity is made up of circles of diffusion formed by diverging beam. The nodal point in myopes is further away from the retina and image formed is larger in size. Accommodation is of little value to myopes for higher errors. The amplitude of accommodation is small.

### **Classification of Myopia**

- a. Congenital Myopia
- b. Simple Myopia
- c. Pathological Myopia
- d. Acquired Myopia

### **Congenital Myopia**

- ✓ Is present since birth
- ✓ Diagnosed by the age of 2-3 years
- ✓ Seen in premature children or in various birth defects such as Marfan's syndrome or Homocysteinuria

- ✓ Is unilateral and manifests as anisometropia
- ✓ Error is about 8 to 10 D associated with congenital squint
- ✓ Associated with cataract, microphthalmos, aniridia, megalocornea and congenital separation of retina

### **Simple Myopia**

Simple or developmental myopia is the commonest type and considered as a physiological error and not associated with any disease of the eye.

Etiology: It results from normal biological variations in development of the eye which may or may not be genetically determined.

**Axial Myopia:** results from the increase in the anteroposterior length of the eyeball. It is the commonest form.

**Curvature Myopia:** results from increase in the radius of curvature of the cornea, lens or both. A variation of 1 mm of radius of curvature results in a refractive change of 6 D.

**Index Myopia:** Here, changes in dioptric system may be due to change in refractive index of lens, cornea, aqueous or vitreous. The dioptric power of the eye is too strong for the axial length of the eye.

**Clinical Symptoms:**

- ✓ Poor vision for distance (short sightedness) is the main symptom of myopia.
- ✓ Asthenopic symptoms occur in patients with small degree of myopia. Eyestrain develops due to dissociation between convergence and accommodation.
- ✓ Fusion becomes weak and binocular vision is affected.
- ✓ Patient starts suppressing one eye and suppressed eye deviates outwards.
- ✓ Decreased visual acuity in indoor activities.

**Signs:**

The eye of simple myopia is large and prominent. Chamber is deep and pupil reaction is sluggish. Macula appears slightly nearer to disc. There may be divergent squint.

**Pathological / Progressive / Degenerative Myopia**

- ❖ It is a rapidly progressive error resulting in high myopia during early adult life, usually associated with degenerative changes in the eye.



- ❖ It results from rapid axial growth of the eyeball outside the normal biological variation of development.
- ❖ It is definitely linked to heredity and general growth process.

Heredity factor: Progressive myopia is familial and more common in races like the Chinese, Japanese, Arabs and Jews.

Role of general growth process: Factors like nutritional deficiency, debilitating diseases, endocrinal disturbances and indifferent general health also influence progress of myopia.

### **Clinical Picture**

- Defective vision
- Night blindness
- Muscae volitantes

### **Signs**

- Eyes are more prominent
- Anterior Chamber is deep
- Cornea appears large
- Pupil slightly large and sluggish
- Refractive error increases by as much as 4D yearly and usually stabilizes at the age of 20.

## **Fundus Picture**

- Optic disc appears large and pale
- Myopic crescent
- Atrophy of retinal pigment epithelium and choriocapillaries- tigroid appearance due to visible prominent large choroidal vessels
- Atrophic patches at macula
- Foster Fuchs spot
- Cystoid degeneration
- Posterior staphyloma
- Posterior vitreous detachment
- Contraction of visual fields
- ERG subnormal

## **Complications**

- Retinal detachment
- Complicated cataract
- Vitreous haemorrhage
- Choroidal haemorrhage

## **Treatment**

### **Non Surgical**

- ✓ Spectacle correction with concave lens
- ✓ Contact lens

### **Surgical**

- ✓ Radial Keratotomy
- ✓ Photo-Refractive-Keratectomy
- ✓ LASIK
- ✓ Intra corneal ring implantation for low myopia
- ✓ Phakic IOLS

## **History**

Refractive surgery has been used to correct myopia and hypermetropia for more than 40 years. Conceptually, refractive corneal surgery attempts to remove, add or modify the corneal stroma, so that the radius of curvature of the anterior corneal interface is altered as desired.

Based on the fundamental principle that cornea contributes twothirds of refracting power of the eye, Barraquer attempted to alter the tear film/ anterior cornea interface radius of curvature by adding or removing corneal tissue.

Keratomileusis in situ- derived from the Greek word keras ( horn-like=cornea) smileusis- carving. Keratomileusis in situ for myopia was the first to develop in late 1940. The procedure involved raising a corneal flap and removing tissue from residual stromal bed. Barraquer performed a free hand lamellar dissection of the anterior half of the cornea with a keratome. Subsequently, refractive cut was attempted with second pass of the knife to remove stromal bed and cap was replaced with flattening of corneal curvature thus reducing myopia. This procedure was abandoned due to many technical difficulties.

The gateway to Keratophakia opened in 1961, which involved steepening of central corneal curvature by placing a disc of tissue under the lamellar cap derived from alloplastic stromal disc harvested from a donor cornea.

This was seen a possible solution in aphakia, but with advent of IOL, interest in keratophakia subsided.

#### Freeze myopic Keratomileusis

In an effort to overcome technical difficulties of manual cut, Barraquer used contact lens lathe to sculpture the frozen lamellar cap. Barraquer recognized that the cutting speed and the relation between FOP and diameter of resection were factors directly affecting quality and depth of cut. His efforts for more predictable and accurate cuts led to the development of applanator

lenses, suction rings of various diameters and various heights of microkeratome tracks. This work constituted the basis of future microkeratome evolution.

**Disadvantages:**

1. Learning curve was too steep with higher complication rate.
2. Cryolathe was too expensive and complex to maintain.

**Epikeratoplasty**

Epikeratophakia was introduced in 1979 by Kaufmann and Werblin to avoid use of cryolathe. They used preprocessed refractive lenticules. A stromal disc was removed from the donor eye with microkeratome and was frozen and lathed into concave or convex lenses and then lyophilized and stored for later use. It was intended for use in myopia, hypermetropia and keratoconus.

**Complications**

1. Persistent epithelial defect
2. Epithelial ingrowth
3. Melting, scarring
4. Epithelialisation of donor lenticule

## Barraquer-Krumeich Swinger (BKS) technique

An improved microkeratome, a set of dyes and suction stand microkeratome was used to perform a total lamellar cap. The cap was placed epithelial side down on suction rings for microkeratome to perform second cut on stromal aspect of cap. The sculptured lamellar disc was finally sutured back to the bed. The nonfreezing technique has more advantage over freeze techniques with rapid and comfortable recovery, preservation of fibroblasts and epithelium. However, significant astigmatism could not be avoided.

## Automated lamellar keratoplasty

Development of automated geared microtome by Ruiz in 1980 introduced Automated lamellar keratoplasty. Speed of the cut could be controlled resulting in more even and consistent cuts.

The second cut was made on the bed. The depth of second cut was adjusted by altering the height of suction ring and corneal cap was sutured back.

## **Advantages**

- ✓ Rapid recovery
- ✓ Efficacy in correcting high myopia
- ✓ Ease of use

## **Disadvantages**

- High degree of irregular astigmatism

## **Photorefractive Keratectomy**

It is a procedure of photoablation by Excimer laser which has been in use for the treatment of myopia, hypermetropia and astigmatism.

Photorefractive keratectomy has gained maximum success in myopic patients. Photorefractive keratectomy has become popular after Srinivasan, Barren and Trokel in 1983 thought that excimer laser can be used to cut the cornea.

Photorefractive keratectomy gives good results from  $-2$  to  $-6$  D of myopia.

## **Indications**

1. Superficial scar with myopia
2. Basement membrane dystrophy with myopia
3. myopia when unable to use a microkeratome because of high brow or tight lid with narrow palpebral fissures
4. Glaucoma suspects
5. cornea thinner than 500 microns

Photorefractive keratectomy can be satisfactorily performed under topical anesthesia. The center of the pupil is marked; the epithelium is removed by mechanical debridement with a blunt hockey knife followed by followed by ablation of corneal stroma with excimer laser. Reepithelialisation occurs in 3 to 4 days. Improvements in the laser profile, small spot size, flying spot technology and Gaussian curve in conjunction with mitomycin C have made it possible to treat higher degrees of myopia. Epithelium can also be removed using alcohol or by excimer laser.

### **Complications are Uncommon Which Include**

1. Corneal haze and regression
2. Night glare and halos
3. Delayed epithelial healing
4. Corneal ulceration
5. Corneal infiltration
6. Central islands
7. Decentration of ablation zone

### **Lasik**

Is a keratorefractive surgery that combines the precision of excimer laser photoablation with advantages of an intrastromal procedure that maintains the integrity of Bowmans layer and overlying epithelium. It was



introduced, designed and developed at University of Crete and Verdin Oyannion Eye Institute of Crete in 1988.

Currently, this procedure is being considered the refractive surgery of choice for myopia because of its definite advantages over PRK and RK. LASIK can be used to correct upto  $-15\text{D}$  of myopia and upto  $-6\text{D}$  of astigmatism depending on the excimer laser platform used.

Mel 80 excimer laser is approved by the FDA for correction of myopia upto  $-7.00\text{ D}$ . It can be used for correcting errors upto  $-15.00\text{D}$ , but it is a “off label” use.

### **Preoperative evaluation**

Marguente Mc Donald MD of New Orleans, Louisiana performed the first PRK and has been one of the key surgeons responsible for extensive pioneering work in appropriate approach to PRK.

A thorough preoperative evaluation is of critical importance in achieving a successful outcome following refractive surgery. During this evaluation, the surgeon decides if the patient is or not a good candidate for refractive surgery.

1. **MEDICAL HISTORY:** It should include history of any systemic disease like diabetes, prior surgeries, connective tissue disorders, and any

immunocompromised states like HIV / AIDS, drug history - isotretinoid, sumatriptan, amiodarone, and hormone replacement therapy.

2. **REALISTIC PATIENT EXPECTATION:** The ophthalmologist should explain in detail about the refractive results. Patients should understand will not prevent possible future ocular problems like cataract, glaucoma or retinal detachment. Patients should be told that PRK is being done to decrease dependence on glasses and not to get rid of glasses.
3. Patient ocular history, blepharitis, recurrent erosion, dry eyes, retinal tears, detachment, use of glasses, stability of current refraction, contact lens history- types of contact lens, duration of contact lens use. Patient should discontinue soft contact lens for at least three days to two weeks prior to surgery. After 40 years, patients who have undergone refractive surgery will need presbyopic correction with glasses and this should be explained to the patient.
4. Uncorrected visual acuity for distance and near should be measured to determine the amount of correction to be performed. Full cycloplegic refraction is mandatory. A final subjective refraction using the autorefractometer, Wascaberrometer values and cycloplegic

refraction should be done by the ophthalmologist and refined using duochrome test.

### **Pupil size**

Pupillary examination involves evaluating pupil size in bright room light and dim illumination, any afferent papillary defect, various techniques to measure the size of the pupil like light amplification pupillometer, infrared pupillometer, Wasca aberrometer.

Large pupil may be one of the risk factors for postoperative glare and halo after refractive surgery. Optical zone should be larger than pupil diameter to prevent glare and haloes.

### **Ocular motility or confrontation fields**

Asymptomatic tropia and phoria may develop symptoms after surgery if change of refraction causes the motility status to break down. Orthoptic evaluation should be done preoperatively. Confrontation fields should be done in all patients.

### **Intraocular pressure**

In patients with glaucoma, lasik elevates the IOP during the procedure, aggravating optic nerve damage.

Topical corticosteroid use after PRK may cause elevation of IOP in corticosteroid responders.

### Slit lamp Examination

Complete slit lamp examination of eye, lids, cornea and anterior segment should be performed to check for meibonitis, sty, blepharitis, tear film stability, conjunctival scarring, pterygium, epithelial erosions, dystrophies, keratoconus or any opacities.

Depth of anterior chamber and lens clarity should be assessed.

### Detailed Fundus Examination

It is important to be certain that the posterior segment is normal. Special attention is given to the optic nerve (glaucoma, optic nerve drusen), peripheral retina (retinal tear, detachment, retinal holes, peripheral degeneration, high myopia) are at increased risk for retinal detachment.

### Corneal Topography

It should be done to rule out keratoconus, contact lens warpage

### Ultra sound Pachymetry

It is done for central corneal thickness.

### Wavefront analysis

This is done by using wavefront aberrometer..

## Informed consent

After evaluation, the surgeon analyses all the information and discusses the possibilities with the patient. Risks and benefits of various medical and surgical alternatives are discussed.

Discussions with the patient should include

- 1) Expected uncorrected visual acuity
- 2) Risk of decreased BCVA, severe visual loss, glare haloes, dry eyes
- 3) Need of distant or reading glasses
- 4) Patient should be given informed consent documents and should sign the form well before the surgery.

## PROCEDURE

In this technique to correct myopia, a central optical zone of anterior corneal stroma is photoablated using Excimer Laser to cause flattening of central cornea.

Surgical steps are:-

1. ANAESTHESIA: PRK can be satisfactorily performed under topical anaesthesia.
2. EPITHELIUM REMOVAL: Deepithelialisation methods include mechanical debridement with blunt blade under topical anaesthesia.

Other deepithelialisation methods include alcohol and photoablative deepithelialisation. Attempt should be made to deepithelialise 0.5mm to 1mm larger area than the desired ablative zone. The time lapsed from the removal of corneal epithelium to the application of laser energy should be minimized to prevent extreme drying or wetting of corneal surface. Always avoid leaving any residual islands of epithelium.

3. ABLATION ZONE DIAMETER: small ablative zones are known to cause symptomatic haloes while night driving. Increasing experience in PRK has shown that the ideal diameter of ablation zone for myopia is 6mm and for hypermetropia is 9mm.
4. FIXATION AND CENTRATION OF THE ABLATION ZONE: some surgeons use hand held suction rings, while others promote the method of self fixation by the patient during ablation. Fixation light on the microscope should be co axial with surgeon's and patient's line of vision.
5. Co-axiality of fixation light should be maintained with the laser light also. It should always be explained to the patient that the clarity of fixation target will decline during ablation, but will be visible and that he should try to fix it. It is always better to patch the fellow eye to prevent cross fixation. Laser beam should be aimed at the center of the pupil.

6. **FLUENCE AND REPETITION RATE:** Changes in fluence and repetition rate affect not only the rate at which tissue is removed and the operation time, but also the surface morphology of the ablated corneal tissue.
7. **SCANNING LASER BEAM:** The laser device can be smaller and cheaper if small diameter circular or narrow slit beam is used for scanning the ablated area.
8. **ASPHERIC ABLATIONS:** This is a unique advantage of PRK. Planned aspheric ablations are made in high myopia, which avoid central islands, thereby decreasing postoperative spherical aberrations. Astigmatism occurring due to naturally, post traumatic, post infective and post surgical correction is done by ablating the superficial cornea in a cylindrical fashion known as toric photoablation.

The laser is centered and focused according to the manufacturer's recommendations. Although the excimer laser beam, a 193nm, is invisible to the human eye, a faint fluorescence of deep blue light is sometimes visible during stromal ablation.

The sound of the laser firing is the main feedback signal to the surgeon along with an alteration in light reflex as the stromal ablation progresses.

In order to attempt to decrease the chance of postoperative corneal haze after PRK in high myopia, a soaked pledget usually 0.2mg/ml mitomycin can be placed on the ablated surface for 30 seconds to two minutes at the end of laser exposure. The cornea is then irrigated with balanced salt solution to remove excess mitomycin to avoid damage to limbal stem cells.

Immediate post ablation methods:

After the procedure is completed, a single drop of antibiotic and NSAID are placed in the eye after a bandage soft contact lens is inserted.

Subsequent postoperative care:

The patient should be followed closely until the epithelium is completely healed, which usually occurs within 72 hrs. As long as the bandage soft contact lens is in place, patients are treated with topical broad spectrum antibiotics and corticosteroids, usually 4 times a day.

Studies have shown that corticosteroids are effective in limiting haze and myopic regression after PRK, particularly after higher myopic corrections when used after bandage soft lens removal. Corticosteroid drops are tapered over 3 to 4 months depending on the corneal haze and refractive outcome. Artificial tears are used frequently.



## EVOLVING TECHNOLOGY:

As the early broad beam Excimer laser systems improved and as surgeon experience increased, PRK results improved markedly. The ablation zone diameter enlarged because small ablation zones, originally selected to limit depth of tissue removal, produced more haze and regression as well as glare and haloes. The larger treatment diameter used today includes optical zones and aspheric peripheral bald zones improve both optical quality and refractive stability in myopia and hyperopic treatments.

Central island elevation has become less common with improvement in beam quality and with development of scanning excimer lasers.

## TRACKING DEVICES:

Two types of tracker technology exist:

- a. Closed loop: High speed oscillating infrared beams scan across the edge of fixed dilated pupil. The beams detect the abrupt change in reflected light at the edge of the pupil. This signal then directs rapidly responding mirrors to create a space-stabilised image and the laser beam is located on the cornea on next image.
- b. Open loop: Uses video to monitor the location of an infrared image of the pupil and to shift the laser beam accordingly.

## COMPLICATIONS:

- 1) **OVERCORRECTION:** of more than +1.0D at one year occurs in less than 5% of myopes. Myopic or hyperopic PRK undergoes regression for at least 3 to 6 months. Refractive stability must be achieved before deciding whether overcorrection requires retreatment.
- 2) **UNDERCORRECTION:** occurs much more frequently at higher degree of myopia because of decreased predictability resulting from the greater frequency and severity of regression. Regression is markedly increased with optical zones of less than 6mm diameter.
- 3) **CENTRAL ISLANDS:** Kreuger RR, McDonnell PJ clinical analysis of steep central islands after excimer laser PRK Arch Ophthalmol 1996 114:377-381 with computer assisted topographic analysis. Corneas show a central region of higher corneal refractive power compared to adjacent paracentral cornea. These are the causes of undercorrection, asphericity and irregular astigmatism. Many theories have been put forward to explain their formation. These include:
  - a) Shock wave formation and ejection of plume of gaseous and particulate debris, which interfere with subsequent proper delivery of laser.
  - b) Undesired optics of the laser or variation in beam homogeneity.
  - c) Differential hydration of the corneal tissue postoperatively.
  - d) Healing being non-uniform leads to greater epithelial hyperplasia centrally.

4) DECENTRATION OF THE ABLATION ZONE: Usually occurs either due to poor alignment with patient fixation or due to eye movements during surgery. These patients experience degeneration of optical performance. Diplopia, glare haloes and induced astigmatism with loss of BCVA are the problems associated with decentration.

Layer decentrations may cause complaints of glare, haloes and decreased visual acuity. The patient may experience more symptoms if the decentration zone is more than 1.0mm. Patients with larger pupil may experience symptoms with smaller amounts of decentration, because the edge of the decentered ablation will more easily be perceived within the patient's visual axis. It can be prevented by proper stabilization of the patient's head and by alertness of the surgeon in stopping the ablation if the patient begins to lose fixation.

5) OPTICAL ABERRATIONS: Some patients report optical aberrations including glare, ghost images and haloes. These symptoms are more prevalent after treatment with smaller ablation zones and after higher attempted correction. These complaints seem to be exacerbated at night and are more prevalent in young myopic patients with large pupillary diameters due to an optical zone that is smaller than entrance pupil under conditions of dim illumination. This problem can be treated with second ablation by increasing diameter to 6mm.

6) CORNEAL HAZE: Wound healing patterns after PRK can be separated into three groups.

- i) Normal healers who have trace to 1+ haze and a refraction of 0 to 1.0D at 1 month.
- ii) Inadequate healers who have no haze and a refraction  $>+1.0D$  beyond the target correction at 1 month.
- iii) Aggressive healers, whose have 1+ or greater haze that increases in month 2 and 3 accompanied by regression of the correction.
- iv) Subepithelial corneal haze typically appears several weeks after PRK, peaks in intensity at 1 to 2 months and gradually disappears during the following 6 to 12 months.
- v) Late onset corneal haze that occurs several months or even 1 year or more postoperatively after a prior period of relatively clear cornea.
- vi) Histologic studies in animals with cornea haze after PRK demonstrate abnormal glycosaminoglycans and or nonlamellar collagen deposited in anterior stroma as a consequence of epithelial-stromal wound healing.
- vii) Topical steroids are useful in resolving the level of haze as well as any refractive regression due to haze. Excimer laser retreatment may be required in cases where have persists beyond 6 months and is associated with regression.

- 7) DELAYED EPITHELIAL HEALING: Keratoconjunctivitis sicca, topical anti-inflammatory drugs, prophylactic antibiotic therapy and bigger debrided area are the commonly known causes for delayed epithelial healing.
- 8) RECURRENT EPITHELIAL EROSIONS: There are known to occur if epithelial defect made before ablation procedure is larger than the ablation zone.
- 9) CORNEAL INFILTRATION: The sterile corneal infiltrates are usually focal but may be multicentric. These appear days to weeks after surgery. If they are central they may cause reduction in visual acuity.
- 10) CORNEAL ULCERATION: Patients getting bandage soft contact lens after PRK are prone for corneal ulcers.
- 11) DECREASED CORNEAL SENSATIONS: patient with high myopia undergoing larger and deeper ablations show reduced sensitivity more than other.
- 12) CORTICOSTEROID INDUCED COMPLICATION: Raised IOP is thought to be due to postoperative topical corticosteroids. Corticosteroid induced glaucoma occurs in 1.5% to 3% of patients using fluoromethasone. 25% of patient using dexamethasone. Other complications that have been reported after PRK are corticosteroid induced induced herpes simple virus keratitis, corticosteroid induced ptosis and corticosteroid induced cataract.
- 13) DRY EYE: condition occurs after PRK as a result of denervation with less severity and denervation.

## Research Review

Bedei et al (2009) reported in a prospective, consecutive, observational study of 124 eyes of 62 patients were divided into two groups of 31 patients, 62 eyes each (Groups A and B). Only Group A was treated with MMC 0.02%. The data of the two groups of eyes, related to the best-corrected visual acuity (BCVA), to the difference of refraction pre- and post-treatment, and to the corneal haze, were analyzed through combined permutation tests by using the NPC Test software.

Bedei et al concluded the application of MMC 0.02% solution immediately after PRK produced lower haze rates and had better predictability and improved efficacy 1 year after treatment.

Gambato et al (2004) studied the role of topical mitomycin C in corneal wound healing (CWH) after photorefractive keratectomy (PRK) in highly myopic eyes. A prospective, double-masked, randomized clinical trial. Seventy-two eyes of 36 patients affected by high (>7 diopters) myopia. At 1 year, corneal haze developed in 20% of corticosteroid-treated eyes, versus 0% of mitomycin C-treated eyes. At 12, 24, and 36 months, corneal confocal microscopy showed activated keratocytes and extracellular matrix significantly more evident in untreated eyes ( $P_s = 0.004, 0.024, \text{ and } 0.046$ , respectively).

Gambato et al concluded that topical intraoperative application of 0.02% mitomycin C can reduce haze formation in highly myopic eyes undergoing PRK.

Hashemi et al (2003) studied the effect of prophylactic application of mitomycin-C on haze formation in photorefractive keratectomy (PRK) for high myopia. 54 eyes of 28 myopic patients were enrolled in this prospective study. All eyes were operated by PRK followed by 0.02% mitomycin-C application for two minutes and washed with 20 ml normal saline afterwards. All eyes were examined thoroughly on the first 7 days and one month after surgery; 48 eyes (88.9%) at 3 and 6 months postoperatively. Hanna grading (in the scale of 0 to 4+) was used for assessment of corneal haze.

Hashemi et al (2003) concluded the efficacy of mitomycin-C in preventing corneal haze after treatment of high myopia with PRK. This method- PRK + mitomycin-C - can be considered an alternative treatment for myopic patients whose corneal thickness is inadequate for laser in situ keratomileusis (LASIK).

Carones et al (2002) studied the prophylactic use of mitomycin-C to inhibit haze formation after excimer laser photorefractive keratectomy (PRK) for medium and high myopia in eyes that were not good candidates for laser

in situ keratomileusis (LASIK). This prospective randomized masked study comprised 60 consecutive eyes (60 patients). The inclusion criteria were a spherical equivalent correction between -6.00 and -10.00 diopters (D) and inadequate corneal thickness to allow a LASIK procedure with a residual stromal thickness of more than 250 microns.

Carones et al concluded prophylactic use of a diluted mitomycin-C 0.02% solution applied intraoperatively in a single dose after PRK produced lower corneal haze rates, better UCVA and BCVA results, and more accurate refractive outcomes than those achieved in the control group.

Nassaralla et al (2007) studied the efficacy and safety of mitomycin C (MMC) 0.02% in inhibiting haze formation after excimer laser photorefractive keratectomy (PRK) for residual myopia following radial keratotomy (RK). A prospective, nonrandomized, noncomparative interventional case series was conducted of 22 eyes (14 patients) with residual myopia after RK.

Nassaralla et al concluded a single intraoperative application of MMC 0.02% for 2 minutes appears to be effective in preventing subepithelial haze after PRK for residual myopia in patients with undercorrection or regression following RK.



Srinivasan et al (2008) reported the efficacy and safety of prophylactic mitomycin C (MMC) during photorefractive keratectomy (PRK) over LASIK flaps for the treatment of residual refractive errors following LASIK. In this single center, retrospective clinical study, 30 eyes of 33 patients (mean age 37.2 years) who had MMC (0.02%, 30 to 120 seconds) during PRK for the treatment of residual refractive errors following myopic LASIK were evaluated.

Srinivasan et al concluded photorefractive keratectomy with prophylactic MMC (0.02%) is a safe and effective option for treating myopic regression following LASIK. A single intraoperative application of 0.02% MMC for as few as 30 seconds was effective in preventing postoperative haze formation.

Wallau and Campos (2008) studied 88 eyes of 44 patients with a minimum estimated ablation depth of 50 microns were randomized to receive PRK with MMC 0.002% for 1 minute in one eye and LASIK in the fellow eye to compare photorefractive keratectomy (PRK) with prophylactic use of mitomycin C (MMC) and LASIK in custom surgeries for myopic astigmatism. He concluded photorefractive keratectomy with MMC appears to be more effective than LASIK in custom surgery for moderate myopia. During 6-month follow-up, no toxic effects of MMC were evident.

Shojaei A, Mohammad-Rabei H, Eslani M, Elahi B, Noorizadeh F. reported long-term evaluation of complications and results of photorefractive keratectomy in myopia: an 8-year follow-up. *Cornea*. 2009 Apr; 28 (3):304-10.

Shojaei et al (2009) evaluated 8-year results of photorefractive keratectomy (PRK) for myopia in terms of safety, efficacy, stability, and late complications. From 371 myopic eyes of 203 patients, who underwent PRK using NIDEK EC-5000 excimer laser with 5.5- to 6-mm ablation zones in Basir Eye Center, Tehran, Iran,

Shojaei et al concluded PRK seems to be a safe, efficient, and stable surgical procedure, and if patients obtain a good result with the initial treatment, then their results are relatively stable over time.

## *MATERIALS AND METHODS*

## **PATIENTS AND METHODS**

Patients with high myopia (-6D to -16D) undergoing PRK and PRK with mitomycin C using the Mel80 Excimer system at the cornea clinic, Institute of Ophthalmology, Joseph Eye Hospital, Trichy, between September 2008 and September 2009.



### **Design**

Prospective, comparative, randomized study

### **Inclusion criteria**

- Superficial scar with myopia
- Basement membrane dystrophy with myopia
- Myopia when unable to use a microkeratome because of high brow or tight lid with narrow palpebral fissure
- Cornea thinner than 500 microns
- Glaucoma suspects

### **Exclusion criteria**

-  Cataract
-  Immunocompromised patients (poor healing, increased risk of infection)

✚ Strabismus

✚ Retinal detachment

A standard protocol was used to collect and document all the details regarding the cases included in the study.

Detailed information about history, complaints, occupation of the patient was taken. This included type of visual problem, duration of symptoms, duration of wearing glasses/ contact lens, frequency of changing glasses, any prior corneal surgery, trauma, any prolonged use of topical medications and any history of systemic disease.

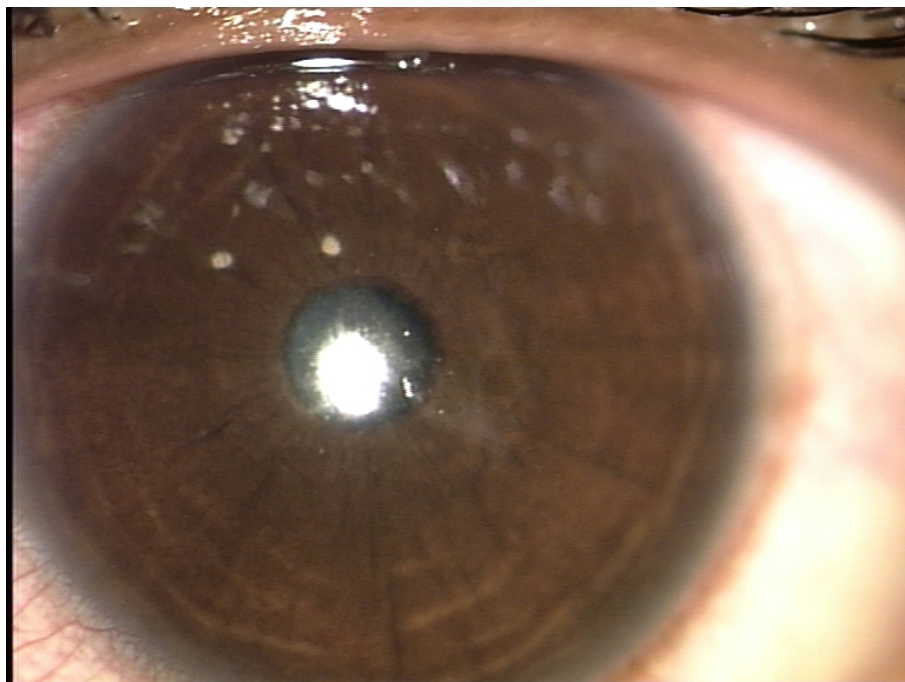
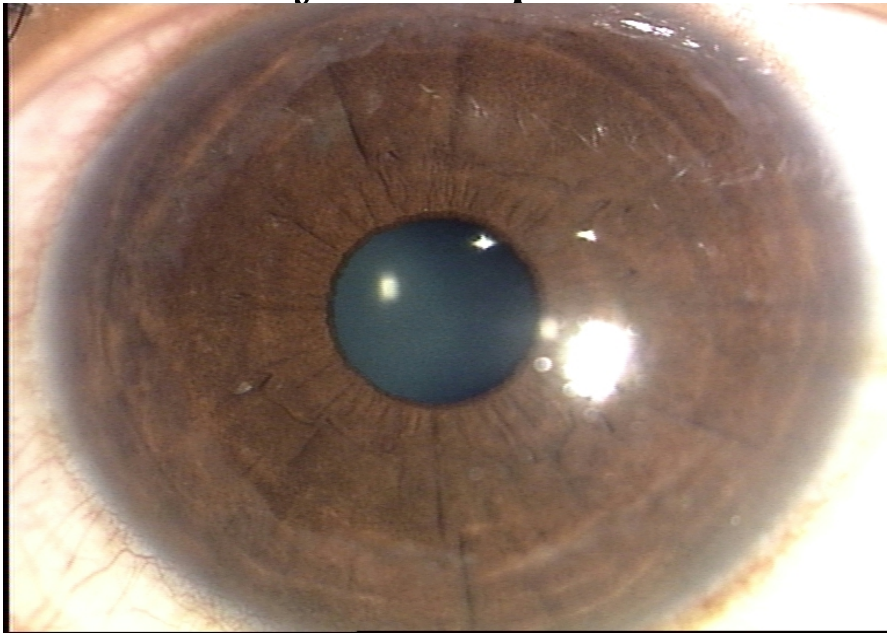
A complete ocular examination was done for each patient which included uncorrected visual acuity, best corrected visual acuity following cycloplegic refraction, slit lamp examination, corneal topography, ultrasound pachymetry, pupillary size, non contact tonometry, slit lamp biomicroscopy with a +90D, indirect ophthalmoscopy and Wasca aberrometer.

- Antibiotic drops (Ofloxacin/ Gatifloxacin) 4 times a day prescribed 1 day before surgery.
- Patient was advised not to use deodorants, perfumes, flowers on the day of surgery to avoid attenuation of laser energy.
- Patient was asked to wash face with soap and water
- Ofloxacin eye drops and NSAID eye drops applied 3 times at 15 min. intervals

- One drop of proparacaine applied 20 min. before scheduled surgery
- Patient was positioned on the laser bed and one more drop of proparacaine applied
- Eyelid margins were prepared with betadine (0.5%)
- Head was draped with towel and speculum applied
- Deepithelialisation was done with blunt hockey knife under topical anaesthesia
- 0.5 to 1.0 mm larger area than desired ablative zone was deepithelialised
- Hand held suction rings were used to fix during ablation
- Fixation light on the microscope was coaxial with surgeon's and patient's line of vision
- The fellow eye was fixed to prevent cross fixation
- Laser beam was aimed at the center of the pupil
- In Mel80 excimer laser, the operating assistant (TOPASS) displays the progress of laser ablation
- After PRK, a soaked pledget with 0.2mg/ml of mitomycin was placed on the ablated surface for 12 seconds at the end of laser procedure
- The cornea is then irrigated with BSS to remove excess mitomycin to avoid damage to limbal stem cells
- After the procedure is completed, a drop of antibiotic and NSAID is instilled and bandage contact lens is placed
- Patient is followed closely until the epithelium is healed in 72 hrs

- As long as the bandage contact lens is in place, patients are treated with topical broad spectrum antibiotics and NSAIDs usually 4 times a day
- Patients are discharged after removal of the bandage contact lens, after 3 days
- The patient was asked to come for follow up on day one, day 3, 1month, 3 months, 6months, and 1 year, when a thorough slit lamp examination was done and visual acuity and refraction recorded.

**First Day Post Operative Picture**



**Three Months Post Operative Picture**





**Wasca Aberrometer**



**Mel 80 Excimer Laser**



**Corneal Pachymetry**



**Corneal Topography**

## *RESULTS*

## RESULTS

In this prospective randomized study 29 eyes were allocated to group 1 and 30 eyes to group 2.

Mean refractive error in group 1 was  $-9.08 \pm 2.86$  D

Mean refractive error in group 2 was  $-9.50 \pm 2.73$  D'

p value = 0.57 (statistically not significant)

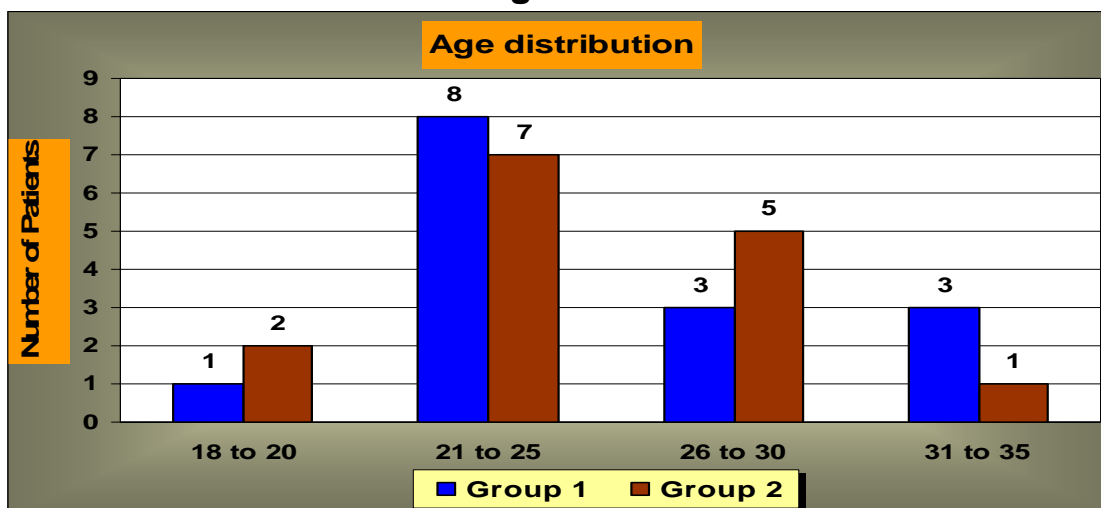
Group 1 underwent PRK and group 2 underwent PRK with mitomycin C.

Patient demographics, age and gender, are indicated in Tables 1-3 and figures 1-3

**Table 1 Age distribution**

Age range	Group 1	Group 2
18 to 20	1	2
21 to 25	8	7
26 to 30	3	5
31 to 35	3	1

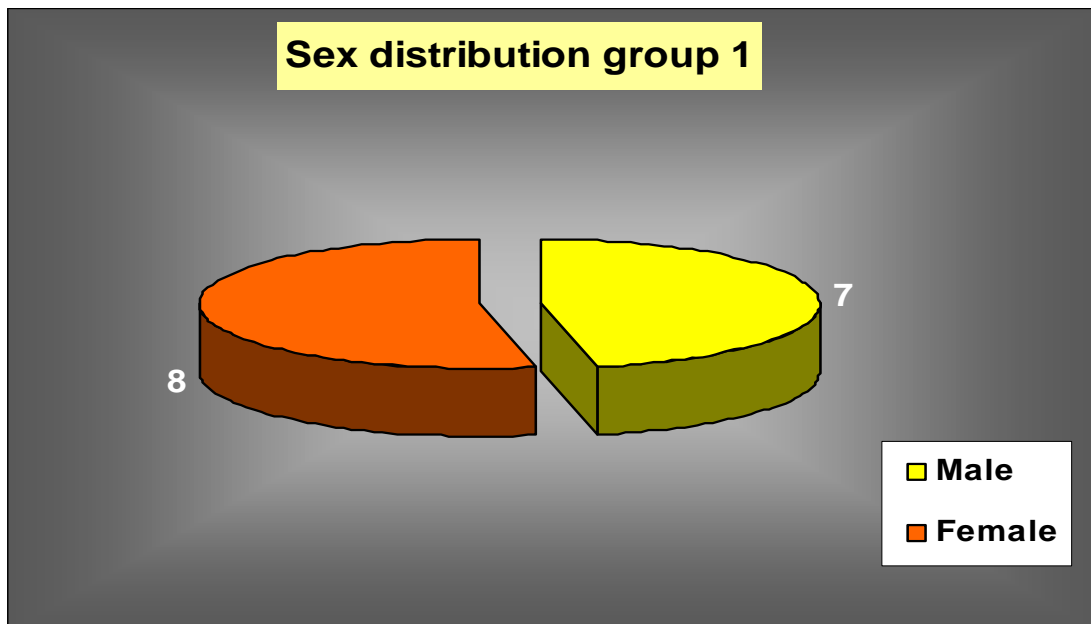
**Figure 1**



**Table 2**  
**Sex distribution in group 1**

S.NO	Sex	No. of Patients
1	Male	7
2	Female	8

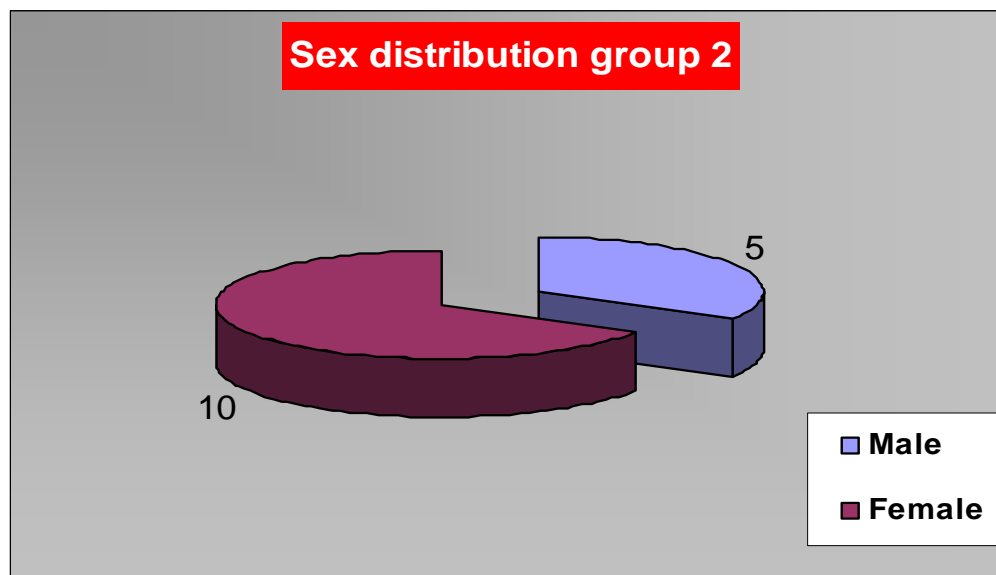
**Figure 2**



**Table 3**  
**Sex distribution group 2**

S.NO	Sex	No. of Patients
1	Male	5
2	Female	10

**Figure 3**



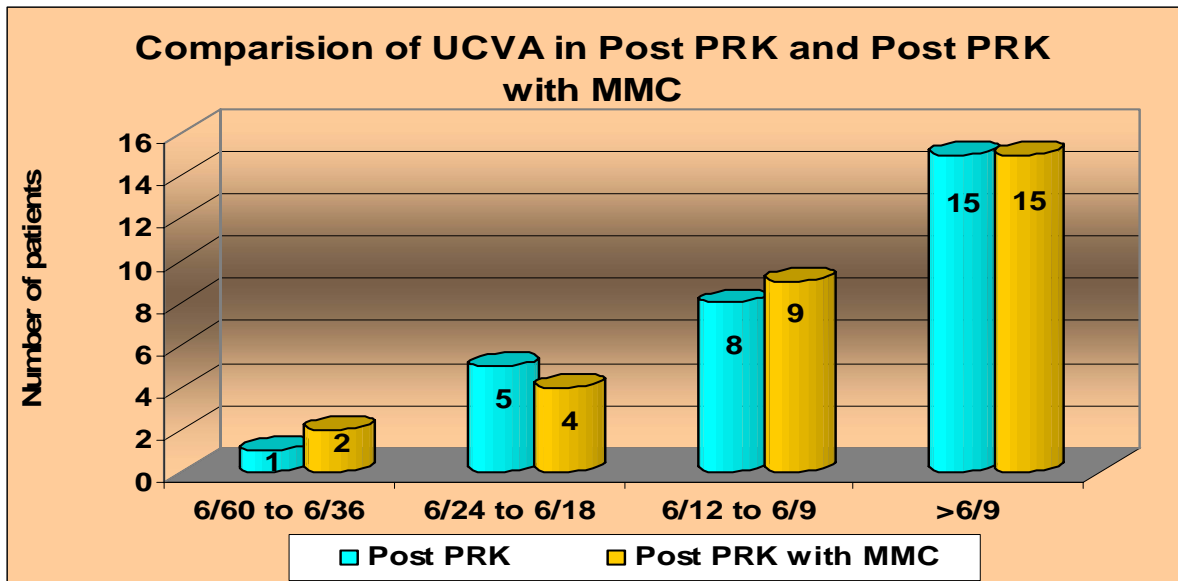
As shown below in Table-4,

After treatment, 15 eyes in each of the groups had UCVA of more than 6/9 (p value=0.018). 8 eyes of group 1 and 9 eyes of group 2 had UCVA of 6/12 to 6/9 (p value=0.042). 5 eyes of group 1 and 4 eyes of group 2 had UCVA of 6/24 to 6/18 (p value=0.174). 1 eye of group 1 and 2 eyes of group 2 had UCVA of 6/60 to 6/36 (p value=0.357).

**Table 4**  
**Post treatment UCVA**

Visual Acuity	Post PRK	Post PRK with MMC	Pvalue
6/60 to 6/36	1	2	0.357
6/24 to 6/18	5	4	0.174
6/12 to 6/9	8	9	0.042
>6/9	15	15	0.018

**Figure 4**



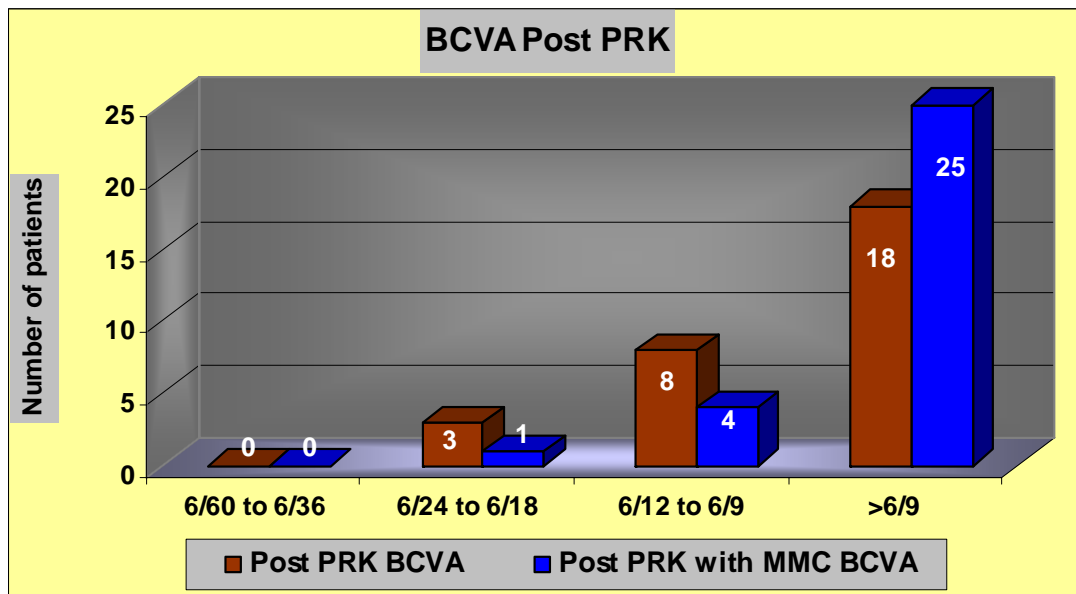
As shown in Table-5,

18 eyes in group 1 and 25 eyes in group 2 had BCVA of more than 6/9 (p value=3.374), 8 eyes of group 1 and 4 eyes of group 2 had BCVA of 6/12 to 6/9 (p value=1.849), 3 eyes of group 1 and 1 eye of group 2 had BCVA of 6/24 to 6/18 (p value=1.147), None of the eyes of both groups had BCVA of less than 6/36 .

**Table 5**  
**Post treatment BCVA**

Visual acuity	Group 1	Group 2
6/60 to 6/36	0	0
6/24 to 6/18	3	1
6/12 to 6/9	8	4
>6/9	18	25

**Figure 5**





As seen in Tables 4 & 5 and figures 4 & 5 , on comparing the visual acuity, it was found that final visual outcome in EACH of the groups was not statistically significant , p value>0.05.

Complications noted are as shown in the table 6 below

**Table 6**  
**Post Treatment Complications**

Complications	Group 1	Group 2
Myopic Regression	10	10
Corneal Haze	12	11
Complicated Cataract	2	0
Transient Glaucoma	0	2

**Myopic Regression:**

Mean myopic regression in Group 1 at the final follow-up of one year was -2.175 D.

Mean myopic regression in Group 2 at the final follow-up of one year was -3.125 D.

There was no significant statistical difference between the two groups for myopic regression. p value=0.26.

**Corneal Haze:**

Corneal Haze was noted in 12 eyes in Group 1 and in 11 eyes in Group 2.

There was no significant statistical difference between the two groups for corneal haze, p value=0.73.

**Complicated Cataract:**

Posterior subcapsular cataract was noted in 2 eyes in Group 1 for which cataract surgery was advised.

**Transient Glaucoma:**

Transient Glaucoma was noted in 2 eyes in Group 2, which was controlled by withholding steroids and instituting anti-glaucoma therapy.

## *DISCUSSION*

## Discussion

In this study, the mean spherical equivalent refraction in Group 1 was  $-9.08 \pm 2.86$  D and in group 2 was  $-9.505 \pm 2.73$  D preoperatively.

At one year, out of 29 eyes in Group 1, in 15 eyes, an UCVA of 6/9 or better was achieved. In the same group, in 18 eyes, BCVA of 6/9 or better was achieved.

At one year, out of 30 eyes in group 2, in 15 eyes, an UCVA of 6/9 or better was achieved. In the same group, in 25 eyes, BCVA of 6/9 or better was achieved.

Corneal haze was noticed at first month follow-up in 12 eyes in group 1 and 11 eyes in group 2. It remained the same at one year. Myopic regression was seen in 10 eyes in each of the groups.

In a similar study, Hashemi et al (2004) the mean spherical equivalent refraction (SE) was  $-7.08$  diopters (D)  $\pm 1.11$  (SD) preoperatively. Six months after surgery, 37 eyes (77.1%) achieved an uncorrected visual acuity (UCVA) of 20/20 or better, all eyes had a UCVA of 20/40 or better and 45 (93.7%) eyes had an SE within  $\pm 1.00$ D. One month postoperatively, 2 eyes (3.7%) had grade 0.5+ of haze, while at 3 and 6 months after surgery no visited eye had haze at all. All eyes had a best corrected visual acuity (BCVA) of 20/40 or better and there were no lost lines in BCVA by 6 months after surgery. In spatial frequencies of 6 and 12 cycles per degree contrast

sensitivity had decreased immediately after PRK and it had increased 1.5 lines by the 6th postoperative month compared to the preoperative data.

In another study, Carones et al (2002), No toxic or side effects were encountered postoperatively. No study group eye had a haze rate higher than 1 during the 6-month follow-up; 19 eyes (63%) in the control group did ( $P = .01$ ). At 6 months, the between-group difference in the refractive outcome was statistically significant ( $P = .05$ ), with 26 study group eyes (87%) and 14 control eyes (47%) within  $\pm 0.50$  D of the attempted correction. No study group eye had a BCVA loss during the follow-up; 7 control eyes had lost 1 to 3 lines at 6 months ( $P = .0006$ ).

Nassaralla et al (2007) described results at twelve months postoperatively, 3 eyes showed grade 1 haze, and 2 eyes showed grade 0.5 haze. Twelve months postoperatively, 2 (9%) eyes had UCVA  $\geq 20/20$ . No eye before and 17 (77%) eyes after treatment had UCVA  $\geq 20/40$ , and no eye before and 9 eyes (40.9%) after treatment had UCVA  $\geq 20/25$ . Best spectacle-corrected visual acuity was  $\geq 20/40$  in all (100%) eyes and 21 (95%) eyes before and after treatment, respectively, and  $\geq 20/25$  in 12 (54.5%) eyes before and after treatment. One (4.5%) eye lost 1 line of BSCVA. Mean spherical equivalent refraction achieved was -0.18 diopters (D) (range: -0.75 to +0.50 D) compared to -2.72 D (range: -1.50 to -4.00 D) before treatment. Twelve months after treatment, 19 (85.5%) eyes had a refractive outcome within  $\pm 0.50$  D.

Wallau and Campos (2008) described Mean spherical equivalent refraction error before surgery and mean ablation depth were  $-3.99 \pm 1.20$  diopters (D) and  $73.09 \pm 14.55$  microm in LASIK eyes, and  $-3.85 \pm 1.12$  D and  $70.7 \pm 14.07$  microm in PRK with MMC eyes, respectively. Uncorrected visual acuity was significantly better in PRK with MMC eyes 3 months ( $P=.04$ ) and 6 months ( $P=.01$ ) after surgery. Best spectacle-corrected visual acuity and spherical equivalent refraction did not differ significantly in the groups during follow-up ( $P>.05$ ). Significant haze was not observed in any PRK with MMC eye. Mean higher order aberration was lower in PRK with MMC eyes postoperatively compared with LASIK eyes ( $P=.01$ ). Better contrast sensitivity was observed in PRK with MMC eyes than LASIK eyes ( $P<.05$ ). The endothelial cell count did not differ significantly between groups ( $P=.65$ ). In terms of visual satisfaction, PRK with MMC eyes were better rated.

Shojaei et al (2009) described follow-up at 8 years after PRK, 69.64%, 44.44%, and 45.65% of the low, moderate, and high myopic groups were within  $\pm 0.5$  D of emmetropia. Sixteen eyes (4.31% of original cases) underwent retreatment mainly because of regression. Although a small myopic shift occurred up to 8 years after surgery, changes in myopic regression stabilized in all myopic groups within 24 months. Four eyes (2.06%) lost 2 lines of best spectacle-corrected visual acuity (1 eye for corneal haze and other 3 for problems not related to refractive surgery).

Corneal haze occurred in 11.34% especially in medium and high myopic groups, but it cleared within 2 years in 68.2% of cases.

Contrary to most studies in literature, viz., Bedei et al,2009; Srinivasan et al,2008; Wallau et al 2008;Hasan Hashemi,2004; gamboto et al, 2004;Carones et al,2002 and others, in this study it was found that addition of Mitomycin C following PRK did not significantly decrease the incidence of the complications, corneal haze and myopic regression, as indicated by the p value.

However, most studies advocating the use of mitomycin C have used it for longer periods on the cornea, viz, 30secs(Srinivasan et al 2008), 1minute ( Wallau et al 2008), 2minutes(Hasan Hashemi,2004).

A possible limitation in this study is that the 0.02% mitomycin C that was used was applied on the cornea for 12 seconds, as suggested by . It is possible that application for longer durations could yield better results.

Also, it remains to be seen if follow-up of the given cases for longer periods could show a difference in the incidence of complications between the two groups.

## *CONCLUSION*



## **Conclusion**

Following PRK and PRK with mitomycin C in high myopia, no difference in the visual outcome was statistically discernable at one year.

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*PROFORMA*

## PROFORMA

### VISUAL OUTCOME OF PRK IN LOW TO MODERATE MYOPIA

NAME OF PATIENT:

AGE:

SEX:

OCCUPATION:

IP No.:

DATE OF ADMISSION:

DATE OF OPERATION:

DATE OF DISCHARGE:

HISTORY:

COMPLAINTS

History of:

1. Wearing spectacles- Duration, last change of glasses
2. Wearing contact lens- Duration, type (soft/rigid/gas permeable PMMA)
3. Previous refractive surgery
4. Disease of the eye
5. Any allergy
6. Previous squint surgery, RD surgery, Laser for retinal holes
7. Pregnancy/ Lactation
8. Social history- Occupation
9. Medical History

### OCULAR EXAMINATION

1. Uncorrected Visual Acuity- Distant Vision: Aided  
Unaided  
Refraction
2. Lids and Adnexa- Chalazion, Blepharitis, Styne
3. Palpebral fissure- Deep socket, Prominent eyes
4. Squint, Nystagmus
5. Conjunctiva- Scarring, Pterygium, Papillae
6. Cornea- Size of the cornea, Clarity, Vascularisation
7. Anterior Chamber
8. Pupil- Size, Shape, Reaction
9. Lens- Opacities, Subluxation

## INVESTIGATIONS:

1. Slit lamp examination- including IOP measurement
2. Corneal Topography- irregular astigmatism
3. Ultrasound pachymetry
4. Indirect Ophthalmoscopy
5. Tear film Stability
6. WASCA aberrometry- 3<sup>rd</sup>, 4<sup>th</sup> aberrations pupil size in dark

## VISION

## RE

## LE

Distant vision- unaided

with pinhole

Refraction - with correction

AR

BCVA

Near vision- unaided

With correction

## PROCEDURE

## POST OPERATIVE EVALUATION

Day 0-visual acuity, refraction, slit lamp examination

Day 1

Day 3

1 month

3 months

6 months

1 year

Remarks